510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

JUN 1 3 2010

Sheila Bruschi
Senior Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 320-4515
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Date Prepared: June 4, 2010

B. Device Name

Trade or Proprietary Name:	*NuVasive CoRoent® XLR Standalone System*
Common or Usual Name:	Intervertebral Body Fusion Device, Spinal Partial Vertebral Body Replacement Device
Classification Name:	Intervertebral Body Fusion Device, Spinal Partial Vertebral Body Replacement Device
Device Class:	Class II
Classification:	§888.3060, §888.3080
Product Code:	MQP, MAX

C. Predicate Devices

The subject *CoRoent® XLR Standalone System* is substantially equivalent to the following predicate devices currently distributed commercially in the U.S.:

- K073109 – SurgiCraft STALIF™ TT System
- K081849 – Blackstone Medical PILLAR™ SA PEEK Spacer System
- K072253 – Synthes SynFix™-LR
- K081501 – Biomet Spine Solitaire™ Anterior Spinal System
- K083475 – Spinal Elements Lucent® Magnum+

D. Device Description

The *NuVasive CoRoent XLR-Standalone System* is an implantable device manufactured from PEEK and titanium alloy that is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

E. Intended Use

When used as an intervertebral body fusion device:
The CoRoent XLR-Standalone System is a standalone system indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or

two contiguous levels in the lumbar spine (L2 to S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The CoRoent XLR-Standalone System is intended for use with autograft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the CoRoent XLR-Standalone System.

When used as a partial Vertebral Body Replacement (VBR):
The CoRoent XLR-Standalone System is a standalone system indicated for use in the thoracolumbar spine (T1-L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The CoRoent XLR-Standalone System is also indicated for treating fractures of the thoracic and lumbar spine. The CoRoent XLR-Standalone System is intended to be used with autograft or allograft.

F. Technological Characteristics

As was established in this submission, the subject *CoRoent XLR-Standalone System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *CoRoent XLR-Standalone System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic torsion per ASTM F2077
- Static and dynamic compression per ASTM F2077
- Wear Debris per ASTM F2077 & ASTM F1877
- Subsidence per ASTM F2267
- Expulsion per ASTM Work Item Z8423Z

The results of these studies showed that the subject *CoRoent XLR-Standalone System* meets or exceeds the performance of the predicate device, and the device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject subject *CoRoent XLR-Standalone System* has

been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NuVasive, Inc.
% Ms. Sheila Bruschi
Senior Regulatory Affairs Associate
7475 Lusk Boulevard
San Diego, California 92121

SEP 12 2011

Re: K100043
Trade/Device Name: NuVasive CoRoent® XLR Standalone System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MQP
Dated: May 18, 2010
Received: May 19, 2010

Dear Ms. Bruschi:

This letter corrects our substantially equivalent letter of June 16, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100043

Device Name: NuVasive® CoRoent® XLR Standalone System

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100043